

REMARKS

I. Introduction

Applicants submit this Amendment in reply to the Office Action dated October 22, 2003. In this Amendment, Applicants have cancelled claim 3, without prejudice or disclaimer, amended claims 1 and 4, and added new claims 86-88 to more clearly define the claimed invention. Claim 1 is the sole independent claim. Before entry of this Amendment, claims 1-6 were pending in this application. After entry of this Amendment, claims 1-2, 4-6, and 86-88 are pending in this application. The originally-filed specification, claims, abstract, and drawings fully support the subject matter of amended claims 1 and 4, and new claims 86-88. No new matter was introduced.

On page 2 of the Office Action, the Examiner objected to claim 1 for an informality. Applicants have amended claim 1 as suggested by the Examiner. Applicants respectfully request withdrawal of the objection.

On page 2 of the Office Action, the Examiner rejected claims 3-4 under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Applicants have cancelled claim 3, without prejudice or disclaimer, rendering the rejection moot.

II. Rejections Based on Ryan and Gelbfish

On pages 3-4 the Office Action, the Examiner rejected claim 1 under 35 U.S.C. §102(b) as being anticipated by Ryan et al. (U.S. Patent No. 5,285,795) ("Ryan") and rejected claim 6 under 35 U.S.C. §103(a) as being unpatentable over Ryan in view of Gelbfish (U.S. Patent No. 5,730,717) ("Gelbfish"). Applicants respectfully traverse these rejections because Ryan, whether taken individually or in combination with Gelbfish,

does not disclose or suggest every aspect of either claims 1 or 6 either alone or in combination with the other aspects of the claimed invention.

Independent claim 1, as amended, recites a biopsy instrument including, among other aspects, a distal assembly that includes "a first jaw and a second jaw pivotable relative to the first jaw." Each of Ryan and Gelbfish clearly does not disclose at least this aspect of the invention, and the Examiner does not rely on either of these references to teach a distal assembly including jaws. Accordingly, Applicants respectfully request the withdrawal of the rejections based on Ryan and Gelbfish.

III. Rejection Based on Huitema and Onik

On page 4 of the Office Action, the Examiner rejected claims 1-5 under 35 U.S.C. §103(a) as being unpatentable over Huitema et al. (U.S. Patent No. 5,562,702) ("Huitema") in view of Onik et al. (U.S. Patent No. Re. 33,258) ("Onik"). Applicants respectfully traverse this rejection.

The examiner bears the initial burden of presenting a *prima facie* case of unpatentability. In re Oetiker, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, the prior art references, when combined, must teach or suggest all aspects of the claim. M.P.E.P. § 2143. As will be explained, this criteria is not met here because the Huitema and Onik references do not teach all of the aspects of claim 1. In addition, a *prima facie* case of obviousness requires some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. M.P.E.P. § 2143. As also will be explained, this

criteria also is not met here because combining the teachings of Onik into the device of Huitema will destroy the function of the Huitema device.

A. Huitema and Onik Do Not Teach All Aspects of the Claims

Independent claim 1, as amended, recites a biopsy instrument including, among other aspects, a distal assembly that includes "a first jaw and a second jaw pivotable relative to the first jaw, the irrigation conduit leading to and in fluid communication with the first jaw, and the aspiration conduit leading to and in fluid communication with the second jaw." Huitema, whether taken individually or in combination with Onik, does not disclose at least these aspects of the invention, either alone or in combination with the other aspects of the claimed invention.

Huitema discloses a shaft tube 47 extending from a housing 34, a lower jaw 61, and an upper jaw 76 mounted on the lower jaw 61. Huitema also discloses that one or both of the jaws may include sensor lines, aspiration conduits, and irrigation conduits. (Fig. 1; col. 13, lines 16-23). However, as the Examiner concedes, Huitema does not teach any features relating to the aspiration and irrigation conduits, (Office Action, page 4), much less the claimed features.

Onik also does not teach the claimed features of the irrigation and aspiration conduits, and therefore does not remedy the deficiencies of Huitema. Onik discloses a discectomy device 12 having a cutting member 42 with a flared cutting edge 44 that severs tissue 78 extending through a port 48. Once severed, the tissue 78 is irrigated by fluid flowing between the outer surface of the elongate tubular cutting member 42 and the inner surface of a central bore 40 of a needle 16, through a slot 50, and down a central bore 52 of the cutting member 42. (Figs. 1-4; col. 4, lines 27-46). However,

because Onik does not disclose jaws, Onik cannot set forth any relationship between an aspiration conduit, irrigation conduit, and jaws, let alone the relationship as set forth in claim 1. Accordingly, because Huitema and Onik do not disclose or suggest every aspect of the claimed invention, a proper case of *prima facie* obviousness cannot be established with respect to independent claim 1, as amended, and its dependent claims 2, 4-6, and 86-88.

B. There is No Motivation to Combine Huitema and Onik as the Combination Would Not Work

The devices of Huitema and Onik operate under vastly different principles. The Huitema device shown in Figs. 1-7, for example, includes a tube 47, a pivot portion including pivot pin 54, and an intricate mechanism for opening and closing of the distal jaws. That mechanism includes a spring 90 which acts against jaw 61 and shaft 86 on the jaw 76 to open the jaws 61, 76. To counteract this opening force exerted by the spring 90, cord 96 enters the inner portion of the jaws 61, 76 from tube 47, wraps around the first and second surfaces 111, 112 of oval lever arm 74, and around arcuate groove 108 of jaw 76. Thus, by pulling the cords 96 away from the jaws 61, 76 and rotating oval lever arm 74, the opening and closing of the jaws 61, 76 may be controlled. (See, for example, Figs. 3-6; col. 11, line 15 through col. 12, line 48).

On the other hand, the Onik device includes a discectomy device 12 having a cutting member 42 with a flared cutting edge 44. The cutting member 42 moves longitudinally relative to the central bore 40 of the needle 16 so as to extend past port 48, and thus sever tissue 78 extending through the port 48. Once severed, the tissue 78 is irrigated and aspirated by fluid flowing between the outer surface of the elongate

tubular cutting member 42 and the inner surface of a central bore 40 of a needle 16, through the slot 50, and down the central bore 52 of the cutting member 42. (Figs. 1-4; col. 4, lines 27-46). Unlike the Huitema device, the Onik device does not include a pivoting feature or an actuation mechanism to open and close jaws that operates through an intricate distal structure, including pullcords, springs, and levers. The Onik device simply includes two concentric tubes that translate relative to one another to obtain a tissue sample.

The Examiner suggests that it would have been obvious to modify the Huitema device with the Onik irrigation and aspiration system. However, modifying the Huitema device to include the irrigation and aspiration portions of Onik would interfere with the intricate workings of the Huitema device. For example, the combination would require the cutting member 42 of Onik, through which aspiration of tissue and irrigation of fluid occurs, to extend through at least several portions of the Huitema device (for example, support member 46, pivot pin 54, oval lever arm 74, elongate slot 84, shaft 86, spring 90, cord 96, first surface 111, and second surface 112) that assist in actuating the jaws 61, 76. This would be required in order for the irrigation and aspiration conduits to lead to and be in fluid connection with the jaws 61, 76, as set forth in claim 1. However, such a modification would prevent the proper actuation and manipulation of the jaws 61, 76, as at least some of the aforementioned portions of the jaws 61, 76 would either be severed, eliminated, and/or require substantial modification by the conduits running therethrough. For example, the placement of the Onik cutting member 42 through the Huitema shaft tube 47 and the inner portion of the Huitema jaws 61, 76 would interfere with the Huitema cords 96, hindering proper actuation of the jaws 61, 76. At a

minimum, Huitema would need to be further modified so that the cutting member 42 and the cords 96 could coexist. Such a modification, however, is not set forth in the references, and would clearly change the principle operation of the invention in Huitema. In another example, the placement of the cutting member 42 through the shaft tube 47 and the inner portion of the jaws 61, 76 may would interfere with the interface between the pivot pin 54 and the support member 46 of Huitema, preventing the jaws 61, 76 from properly rotating relative to the upper and lower brackets 42, 44 of Huitema. This also would render the invention in Huitema unsatisfactory for its intended purpose.

Put simply, the actuation mechanism of Huitema would require substantial modification, not taught by the references, in order to accommodate the Onik aspiration and irrigation system. The combination is impermissible as modifications to the Huitema device would change the principle of operation of the prior art invention being modified, In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959), and render the prior art invention being modified unsatisfactory for its intended purpose. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Accordingly, because Huitema and Onik cannot be properly combined a proper case of *prima facie* obviousness cannot be established with respect to independent claim 1, as amended, and its dependent claims 2, 4-6, and 86-88.

IV. Conclusion

Applicants further submit that claims 2, 4-6, and 86-88, which depend from independent claim 1, are allowable for at least the same reasons that independent claim 1 is allowable. In addition, at least some of the dependent claims recite unique

combinations that are neither taught nor suggested by any of the cited refereces, and therefore at least some also are separately patentable.

In view of the foregoing remarks, this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, abstract, and drawings in this Amendment, Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification or abstract and/or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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